REMARKS

Claim amendments

Claims 26 and 28-29 34-35 and 71-72 are pending herein. Claims 26 and 34 have been amended to track the language of the issued compound claims of US Patent No. 7262286, which has an identical specification. Claims 71 and 72 have been amended to recite an "immunostimulatory oligonucleotide compound", as recited in the claims on which they depend. No new matter has been added.

Written description

Claims 26, 28-29, 34-35 and 71-72 are currently rejected as failing to meet the written description requirement.

Claims 26 and 34 have been amended to track the language of the issued compound claims of US Patent No. 7262286, which has an identical specification. Since the PTO has already determined that the compound claims of US Patent No. 7262286 meet the written description requirement, Applicants respectfully submit that the pending claims, to the use of those same compounds, also satisfy the written description requirement.

Applicants also reiterate and incorporate by reference the argument submitted in Applicants' reply dated December 4, 2008, based upon *Capon v. Eshar*, 418 F.3d 1349, 76 U.S.P.Q.2d 1078 (Fed. Cir. 2005):

As noted therein, the court stated in *Capon*,

> The "written description" requirement must be applied in the context of the particular invention and the state of the knowledge. The Board's rule that the nucleotide sequences of the chimeric genes must be fully presented, although the nucleotide sequences of the component DNA are known, is an inappropriate generalization. When the prior art includes the nucleotide information, precedent does not set a *per se* rule that the information must be determined afresh. .... The "written description" requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.

In the present case Applicants' contribution was that replacement of cytosine in a CpG dinucleotide of an immunostimulatory CpG-containing oligonucleotide by 5-hydroxycytosine, 5-hydroxymethylcytosine, N4-alkylcytosine or 4-thiouracil would not diminish and may enhance the immunostimulatory activity of any such oligonucleotide. As in *Capon*, the sequences of

CpG-containing immunostimulatory oligonucleotides were already known in the art, and thus there was no need to reiterate that knowledge in the present specification. One skilled in the art would recognize that Applicants' contribution would apply to any of those immunostimulatory oligonucleotide compounds.

The Office Action also notes that not all CpG-ODN optimally stimulate immunity in all species (see OA at page 5). However, this alone does not destroy Applicants' written description.

As the court stated in *Capon*,

> It is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention. *See In re Angstadt,* 537 F.2d 498, 504 (CCPA 1976) ("The examples, both operative and inoperative, are the best guidance this art permits, as far as we can conclude from the record"). While the Board is correct that a generic invention requires adequate support, the sufficiency of the support must be determined in the particular case.

In the present case, one skilled in the art would simply look to the previously existing immunostimulatory oligonucleotides to recognize whether any particular embodiment of the claimed invention would be operative. If a given CpG-containing oligonucleotide selected from the prior art is immunostimulatory, its sequence will remain immunostimulatory (and perhaps be improved) with Applicants' modification in Applicants' claimed method. If it is not, it will likely continue to not be operative with Applicants' modification in Applicants' claimed method.

In summary, Applicants' respectfully submit that when what was known in the art at the time of Applicants' filing, and Applicants' contribution to the art is also properly considered, it becomes readily apparent that the written description is satisfied in the present case. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Indefiniteness

Claims 71-72 are currently rejected as being indefinite.

Claims 71 and 72 have been amended to replace the term "oligonucleotide analog immunostimulatory compound" with the term "immunostimulatory oligonucleotide compound". Since this latter term is the term used in claims 26 and 34, from which claims 71 and 72 respectively depend, Applicants respectfully submit that claims 71 and 72 now have proper antecedent basis and request that this rejection be withdrawn.

Enablement

Claims 34-35 and 72 are currently rejected as failing to meet the enablement requirement.

Applicants respectfully submit that claims 34-35 and 72 are adequately enabled by the specification. The Office Action points out the failures of previous attempts to develop effective cancer vaccines. For example, the Office Action, relying upon Bitton, recites:

> Further, most of the vaccines are still experimental and their clinical utility is almost negligible (abstract). Bitton teaches that therapeutic vaccines have proved to have little use in cancer treatment and that in fact in almost every well-designed, well-controlled, randomized phase III trial, they have failed to demonstrate any significant improvement in overall or disease-free survival. ..... The implementation of well-designed randomized phase III trials is urgently required.

(OA at page 9, lines 13-23)

Applicants respectfully submit that the presently maintained rejection simply sets the bar too high for patentable enablement. For patentable enablement, it is not required that a patent disclosure enable one of ordinary skill in the art to make and use a perfected commercially viable embodiment. An instructive case on this point was decided by the Federal Circuit in *CFMT, Inc. v. YieldUp Int'l Corp.,* 349 F.3d 1333, 1338 (Fed.Cir.2003). In *CFMT,* the defendant based its argument for invalidity due to nonenablement on the problems that the patentee encountered in developing a commercial embodiment of the invention. *Id.* at 1336. The district court had concluded that the patent was invalid because it did not enable an embodiment which met commercial standards. *Id.* at 1338. The Federal Circuit reversed, holding that:

> "the district court set the enablement bar too high. Enablement does not require an inventor to meet lofty standards for success in the commercial marketplace. Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.... The lengthy experiments [ ] do not show nonenablement because the inventors undertook that work to satisfy [the patentee's] particular commercial requirements, not to show enablement of the scope of the claimed inventions." *Id.* at 1338-1339.

This case has been extended to lengthy experiments required to satisfy FDA requirements. [*Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, Westlaw 2865469 (D. N.J. 2006) "Similarly, in the instant case, the lengthy experiments needed to obtain FDA approval were done to satisfy Ortho's particular commercial requirements. Section 112, paragraph 1, does not require enablement of commercial success, absent a claim limitation to that effect."]

As in *CFMT* and *Ortho*, the present rejection relies on the failure of a large number of potential anti-cancer drugs to win approval from the FDA, i.e., to be commercially successful. The FDA standards are indeed very high. This is because the mission of the FDA is very different from that of the USPTO. For commercial success, one must obtain FDA approval by showing both safety and efficacy that is superior to existing so-called "gold standard" therapeutic approaches. This is important, because the consequences of approving a new anti-cancer drug are that doctors will be free to use it to treat cancer, potentially in lieu of a safer and/or more effective drug. Thus, it is the FDA's mission to protect the public from such dire consequences.

In contrast, the PTO can grant only a right for the patentee to exclude others from using the claimed invention. Thus, in the present case, if the claimed method of the instant claims are patented, but do not become approved by the FDA for treating cancer, the only consequence would be that Applicants would be able to prevent others from using a commercially unsuccessful, unapproved method.

Thus, the only experimentation required to demonstrate the enablement of the invention is to show that the claimed invention provides an immune response that may be beneficial in treating cancer. This, Applicants have done.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner believes that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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